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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,213	08/05/2003	David Haffner	GLAUKO.011CPI	6863

20995 7590 06/25/2007  
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EXAMINER
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DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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06/25/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

**Office Action Summary**

Application No.

10/634,213

Applicant(s)

HAFFNER ET AL.

Examiner

Glenn K. Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-9, 11, 12, 15-32, 35-39 and 52-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-9, 11, 12, 27, 28, 37 and 53-60 is/are allowed.
- 6) ☒ Claim(s) 15-26, 29-32, 35, 36, 38, 39 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>04-02-2007</u> . | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04-02-2007 has been entered.

***Information Disclosure Statement***

"Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action."

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not provide antecedent basis for the cutting edge of the trocar to be sharp enough to cut through the wall of Schlemm's canal but not sharp enough to significantly damage a scleral wall of the canal.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32, it is unclear how an incision can be made into a space. The incision is made through tissue. Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Paraschac, et al.-6050999.

Paraschac discloses a method of treating an eye condition (hyperopia) including the steps of serially dispensing a plurality of preloaded implants 40 from an instrument 50 to a plurality of locations (immediately adjacent each other) within a space in the eye. The implants are placed by inserting the implanting instrument through an incision and the instrument is not removed from the incision until a plurality of implants are placed in the space. In order to dispense the implants at least a portion of the device must move

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(i.e. the plunger 58,68). Additionally, since the implants would be placed in different locations, the device would inherently need to move to reach these different locations.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section. 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-26,29-32,35,36,38,39 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smedley, et al.-2003/0088260 (or Hill-6533768 in view of Smedley) in view of Poncet-'694, or Paraschac, et al.-'999 or Elliott-6530896.

Smedley discloses the basic instrument and method of use as laid out in the last office action, with the exception of the placing of multiple implants into the body and serially dispensing them into the claimed locations in the eye. However, each of the above references teaches of a dispensing body used to dispense a plurality of implants into a patient's body. Additionally, providing duplicates of known elements has long been determined to be an obvious modification to one skilled in the art. It would have been obvious to have placed several implants into the body of Smedley, as this would allow for the implantation of numerous implants into an eye through the same incision which would allow for faster recovery time and would also allow for a quicker removal of fluid from the eye which is a cause of glaucoma. Smedley also discloses in paragraphs 143 and 144 that the procedure to remove the cataract and implant a trabecular stent can be performed through the same incision.

Hill discloses the device and method as claimed with the exception of the placing of multiple implants into the body and serially dispensing them into the claimed locations in the eye, and the performance of a cataract procedure through the same incision. Smedley discloses a procedure to remove the cataract and implant a trabecular stent can be performed through the same incision. It would have been obvious to have performed a cataract procedure through the same incision as this would allow for the

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replacement of the natural lens with an IOL and the relieving of intraocular pressure with the stent, all of which being performed through one incision speeds recovery.

***Allowable Subject Matter***

Claims 5-9,11,12,27,28,37 and 53-60 are allowed.

***Response to Arguments***

Applicant's arguments filed 04-02-2007 have been fully considered but they are not persuasive.

The examiner contends that since Smedley discloses the placement of the outlets in different locations, including collecting channels, that one skilled in the art would recognize that in an eye having dangerous internal pressures, that given the different disclosed locations for placement of the stent, that the mere duplication of the dispensing steps to implant a second stent into a secondary location would merely increase the rate of outflow and bring the internal fluid pressure under control much more quickly. The fact that low ocular pressure is also detrimental, one skilled in the art would realize that increasing outflow may be beneficial in patients with extremely high IOP and that the physician would merely take appropriate precautions to ensure that dangerously low IOP did not result.

The recovery time that the examiner was referring to was the recovery from dangerously high IOP, not the recovery time from the implant procedure. Additionally, the recovery time from the implant procedure would be less if the device were used through a single incision instead of several. There is no evidence that increasing the

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number of implants would necessarily cause dangerously low IOP. One skilled in the art would know to tailor the implants to increase the overall outflow by increasing the number of implants, but not to the extent that the pressure would become dangerously low.

Paraschak discloses the implantation of a plurality of ocular implants into a space and through a single incision. The claim does not presently require the space to be empty. The space could be everywhere underneath the very top layer of the cornea, but which is filled or has other tissue or structures therein.

### ***Conclusion***

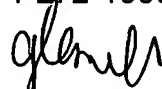
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
19 June 2007